Application No. 10/517,275
Filed on November 20, 2007
Response to Office Action dated May 21, 2007

Remarks:

Claims 22, 24, 27, 47, 48 and 55-61 now stand in this application. Claims 22, 24, 27, 47 and 48 remain unchanged. New claims 55 to 61 have been added in order to protect further therapeutic aspects that have been described in the present specification.

With respect to elections/restrictions, Applicants respectfully request that Examiner consider rejoinder of claim 53. Claim 53 is directed to a method for the treatment of autoimmune disorders and transplantation rejections in a mammalian subject which includes the recitation of "suppresses T cell activity" in common with this same recitation in claim 47, as well as newly added newly claim 55. Thus, claim 53 and claims dependent therefrom should be included for continued prosecution in this application. Rejoinder of claim 53 is respectfully requested.

SEQUENCE COMPLIANCE:

Pursuant to the Examiner's objection under 37 CFR 1.821 to 1.825, the specification has been amended to insert sequence identifiers corresponding to sequences recited at pages 27 and 28.

Applicants have thoroughly reviewed the other pages of the specification and believe that there are no other instances of sequences recited without a corresponding sequence identifier. Thus, the application is submitted to be compliant with the requirements of 37 CFR 1.821 through 1.825.

CLAIM REJECTIONS UNDER 35 USC § 101 and 35 USC § 112:

In the Office Action, claims 22, 24 and 27 are rejected under 35 USC § 112, second paragraph, as well as under 35 USC § 101 for not setting forth any steps involved in a method/process. These rejections are moot, for at least the reason that claims 22, 24 and 27 are directed to the use of a composition of matter, and therefore do not need to be defined in terms of active method/process steps. Instead, claims 22, 24 and 27 are defined by properties and utility of a composition of matter. For at least these reasons, withdrawal of each of

Application No. 10/517,275
Filed on November 20, 2007
Response to Office Action dated May 21, 2007

Examiner's rejections under 35 USC § 101 and 35 USC § 112 is respectfully requested.

CLAIMS REJECTIONS UNDER 35 U.S.C. §. 102 and 35 USC § 103:

In the Office Action, claim 47 is rejected under 35 USC § 102(e) as being anticipated by U.S. 2003/0180301 (Keshavjee). Furthermore, claims 47 and 48 are rejected under 35 USC § 103(a) as being unpatentable over Keshavjee in view of Hammond and Tuschl. Applicants respectfully traverse each of these rejections.

The citation of Keshavjee is submitted to be incorrect. Keshavjee has a filing date of January 21, 2003 and a publication date of September 25, 2003. Both of these dates occur well after the June 10, 2002 priority date of the present application. Furthermore, for completeness the following remarks are offered in respect of Keshavjee.

Keshvajee teaches administration of a TGF-β cytokine antagonist to treat or prevent rejection of transplanted organs or tissues. More specifically, Keshavjee teaches administration of a pharmaceutically effective amount of a TGF-β antagonist to reduce or inhibit fibrosis in an organ transplant (for example see paragraph [0010] and paragraph [0041]). Keshavjee only addresses fibrosis by use of a TGF-β antagonist. Keshavjee does not use the TGF-β antagonist to other any type of immune response or immune disorder. The only mention of "immune" found in Keshavjee is at paragraph [0039]. Here Keshvajee teaches that the use of a TGF-β antagonist encoded within an adenoviral vector may be limited by a host immune response that induces inflammation. Keshavjee goes on to specify that "transplantion immunosuppression attenuates the post-transfection host immune response to adenoviral-mediated gene transfection and thereby increases and prolongs transgene expression". Thus, in Keshavjee the immune response is suppressed by a mechanism other than one involving TGF-β antagonist, and due to transplantion immunosuppression the use of the TGF-β antagonist encoded within an adenoviral vector is found to be effective. Thus, Keshavjee is not relevant to modulation or suppression of an immune response

with a nucleic acid construct. Furthermore, no mention of "T cell" or "T cell activity" could be found after a thorough review of the entire Keshavjee document.

In contrast, claim 47 of the present application not only specifically recites "T cell activity" but also further specifies "a composition that suppresses T cell activity". Examiner will kindly note that this same recitation is found within newly added claim 55. Furthermore, Examiner will please note that this recitation is incorporated by virtue of dependency by claim 48 and newly added claims 56-61.

With respect to the other prior art references cited in the Office Action, Hammond Tuschl, both of these references relate generally to the field of siRNA and provide no specific teaching for modulation of immune cell activity, and certainly do not specifically teach "a composition that suppresses T cell activity".

For at least these reasons, withdrawal of each of Examiner's rejections under 35 USC § 102 and 35 USC §103 is respectfully requested.

Applicant respectfully requests reconsideration of the application. The Examiner may contact the undersigned should any clarification be required.

Respectfully submitted,
SIM & MCBURNEY

By _____

Lola A. Bartoszewicz, Ph.D.
Reg. No: 43,394
Tel: 416 849 8420

LAB/JC/dmd